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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/608,915

06/27/2003

Stephen L. Hoffman

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EXAMINER

WHALEY, PABLO S

ART UNIT

PAPER NUMBER

1631

NOTIFICATION DATE

DELIVERY MODE

03/24/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/608,915	<b>Applicant(s)</b> HOFFMAN ET AL.	
	<b>Examiner</b> PABLO WHALEY	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 85-92 and 107-118 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 85-92 and 107-118 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Status of Claims***

Claims 85-92 and 107-118 are pending.

Claims 85-92 and 107-118 are rejected.

Claims 1-84 and 93-106 have been cancelled.

### ***Priority***

This application has been granted the benefit of priority to US Provisional Application 60/392,843, filed June 28, 2002.

### ***Withdrawn Rejections***

The rejection of claims 85-92, 107-113, and 115-118 under 35 U.S.C. 101 is withdrawn in view of applicant's amendments filed 11/19/2008.

The rejection of claims 85-92 and 109-118 under 35 U.S.C. 103(a) as being obvious by Daniel et al. in view of Wang et al. is withdrawn in view of applicant's arguments filed 11/19/2008.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the

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examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 85-92 and 109-118 are rejected under 35 U.S.C. 103(a) as being obvious by Altuvia (1997, IDS filed 08/27/2004), in view of Gulukota et al. (J. Mol. Biol., 1997, Vol. 267, p.1258-1267), and in view of Daniel et al. (Journal of Immunology, 1998, Vol. 162, No. 2, p.617-624).

**This rejection is newly applied.**

Altuvia teaches a computer-based method for assessing the binding affinity between peptides and four different MHC-class 1 proteins [Abstract, and p.2, Col. 2, p.4, Results, p.8, Col. 2, Fig. 3]. Altuvia obtains peptides sequences with known binding data and affinity for MHC class 1 proteins [p.4, Results]. Altuvia shows extracting peptide sequence data from the SWISSPROT database [p.5, Col. 2, and Table 5]. Altuvia teaches a structure-based predictive algorithm (threading algorithm) for obtaining binding affinity data between candidate peptides and MHC class 1 proteins (HLA-A2) [p.3, Col. 1]. Peptides including 8-mer, 9-mer, and 10-mers [p.3, Col. 2]. Altuvia shows calculating an interaction energy for each different templates in the MHC protein used for threading the candidate peptide, and averaging the results for each of the different templates [p.3, Col. 2], which suggests combining binding affinity data. Altuvia also shows determining binding affinity based on measured IC50 values and correlation to energy values [p.4, Col. 1, Table 2].

Altuvia does not specifically teach determining a second binding affinity using a second predictive method that is different from the first predictive method, as in claims 85, 90, 107, 109, 110, 111, 112, 118.

Altuvia does not specifically teach combining and evaluating first and second binding affinities between a candidate peptide and a target protein, as in claims 85, 90, 107, 109, 110, 111, 112, 118.

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Altuvia does not teach scaling binding affinities from 0 to 1, as in claims 85, 90, 107-112, and 118. However, it would have been obvious to one of ordinary skill in the art to substitute the scaling range from 0 to 10, taught by Daniel, with the scaling range from 0 to 1 with predictable results, since choosing appropriate scaling ranges for data is an arbitrary design consideration.

Gulukota teaches a method for assessing the binding affinity between a candidate peptide and MHC-class 1 proteins [Abstract]. In particular, Gulukota obtains sequence data for a plurality of peptides, and obtains binding strength for at least one peptide for an MHC protein [p.1259, Col. 2, ¶2, Fig. 1, Table 1, and p.1265, Col. 1]. Gulukota teaches neural network and polynomial methods for predicting peptides with binding affinities above a specific  $IC_{50}$  value [p.1259, Col. 2, Results, p.1265-1266]. Gulukota also teaches combining these two methods into the sample program [p.1264, Col. 2, ¶2]. Gulukota teaches ranking binding affinity data ( $IC_{50}$  values) for candidate peptides [p.1263, Col. 2].

Daniel teaches a method for assessing the binding affinities between TAP proteins and peptides [Abstract, p.618, Col. 2, ¶4 and ¶5, and p.620]. In particular, Daniel teaches the normalization of binding affinity values ( $IC_{50}$  values) by scaling the data between 0 and 10 [p.618, Col. 2, ¶4, p.619, Col. 2, ¶5, p.620, Col. 2, ¶1, Tables I and II], which shows the scaling of binding affinity data from 0 to 10. Daniel teaches outputting scaled binding affinity scores [Fig. 3 and Fig. 4]. The motivation would have been improve the graphical representing of data [p.618, Col. 2, ¶4, and Fig. 2].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the binding affinity prediction method of Altuvia by determining a second binding affinity using a second predictive method that is different from the first predictive method, as in claims 85, 90, 107, 109, 110, 111, 112, 118, since Altuvia determines binding affinity based on measured  $IC_{50}$  values correlated to energy values [p.4, Col. 1, Table 2], and since Gulukota teaches neural network and polynomial methods for predicting peptides with binding affinities based on  $IC_{50}$  values [p.1259, Col. 2,

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Results, p.1265-1266]. The motivation would have been to improve the "predictive power" by using multiple measures of goodness and increasing sensitivity, as suggested by Gulukota [p.1264, Col. 2, ¶2].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the binding affinity prediction method of Altuvia by combining and evaluating first and second binding affinities between a candidate peptide and a target protein, as in claims 85, 90, 107, 109, 110, 111, 112, 118, since Altuvia shows averaging binding energy results for each of the different templates [p.3, Col. 2], which suggests combining binding affinity data, and since Gulukota teaches neural network and polynomial methods for predicting peptides with binding affinities and suggests combining these two methods in one program [p.1264, Col. 2, ¶2]. The motivation would have been to decrease the number of false-negatives and false-positives, as suggested by Gulukota [p.1264, Col. 2, ¶2].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the binding affinity prediction method of Altuvia by scaling binding affinities from 0 to 1, as in claims 85, 90, 107-112, and 118, since Daniel teaches the normalization of binding affinity values (IC50 values) by scaling the data between 0 and 10 [p.618, Col. 2, ¶4, p.619, Col. 2, ¶5 and p.620, Col. 2, ¶1, Tables I and II], and outputting scaled binding affinity scores [Fig. 3 and Fig. 4], and since choosing appropriate scaling ranges for data is an arbitrary design consideration. The motivation would have been to improve the graphical representation of data, as suggested by Daniel [p.618, Col. 2, ¶4, and Fig. 2].

### ***Response to Arguments***

Applicant's arguments, filed 11/19/2008, that Daniel does not teach predicting binding affinities between MHC proteins and epitopes have been fully considered and are persuasive. Therefore the rejection the rejection of claims 85-92 and 109-118 under 35 U.S.C. 103(a) as being obvious by Daniel et al. in view of Wang et al. is withdrawn.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**/Pablo S. Whaley/**

Patent Examiner

Art Unit 1631

**/John S. Brusca/**

Primary Examiner, Art Unit 1631